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Telecopier No.:	(703) 872-9307
Client/Matter No.:	U.S. Serial No. 09/485,421; Our Docket No. UPVG-0191
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COVER MESSAGE:

Attached is:

1) Amendment Transmittal Letter; and
2) Amendment and Request for Reconsideration.

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SHOULD ANY DEFICIENCIES APPEAR with respect to this application, including deficiencies in payment of fees, missing parts of the application or otherwise, the United States Patent and Trademark Office is respectfully requested to promptly notify the undersigned.

Date: July 9, 2002

Chad Ziegler
Registration No. 44,273

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DOCKET NO.: UPVG-0191 **PATENT**

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP NO. 1632

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Mahalingam, Ayyavoo, Patel, Kleber-Emmons, and Weiner

Serial No.: **09/485,421** Group Art Unit: **1632**

Filed: **October 5, 2000** Examiner: **Q. Li**

For: **FUNCTIONAL FRAGMENTS OF HIV-1 VPR PROTEIN AND METHODS OF USING THE SAME**

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On **July 9, 2002**

Chad Ziegler Reg. No. 44,275

BOX AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

AMENDMENT AND REQUEST FOR RECONSIDERATION

In response to the Office Action mailed April 9, 2002 in connection with the above-identified patent application, Applicant respectfully requests that the application be amended as follows.

In the Claims:

Please amend claims 1-4 and 7 to read as follows:

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anticipate a claim, however, a prior art reference **must** disclose every feature of the claimed invention, either explicitly or inherently. *Glaxo v. Novopharm, Ltd.*, 334 U.S.P.Q.2d 1565 (Fed. Cir. 1995). Further, to serve as an anticipation when a reference is silent about the alleged inherent characteristic, such gap in the reference may be filled by extrinsic evidence. Such evidence, however, must make clear that the missing descriptive matter is necessarily (*i.e.*, always) present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art. *In re Oelrich*, 40 U.S.P.Q. 323 (C.C.P.A. 1981); *Continental Can Co. USA Inc. v. Monsanto Co.*, 20 U.S.P.Q.2d 1746 (Fed. Cir. 1991). Inherency may not be established by probabilities or possibilities. *Id.* Further, the mere fact that a certain thing ***may*** result from a given set of circumstances ***is not*** sufficient. *Id.* Significantly, the Office Action has not established that the critical inherent characteristics are ***necessarily*** present in the Weiner reference.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C § 102(b) be withdrawn.

II. The Claimed Inventions Are Not Obvious

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of the Weiner reference and U.S. Patent No. 6,005,004 (hereinafter, the "Katz reference") or U.S. Patent No. 6,232,295 (hereinafter, the "Kayyem reference"). The Office Action mistakenly asserts that it would have been *prima facie* obvious for one skilled in the art to modify the methods of the Weiner reference by adding a polycationic peptide sequence of the Katz or Kayyem references to the Vpr conjugate composition. Applicants traverse the rejection and respectfully request reconsideration because even if the cited references are combined, the claimed invention would not be produced.

The Office Action asserts that the Weiner reference does not teach a polycationic amino acid sequence. Therefore, the Office Action attempts to cure such a deficiency by citing the Katz and Kayyem references. For the sake of brevity, the statements made above regarding the Weiner reference are incorporated herein by reference in their entirety. The Weiner reference does not teach or suggest fragments of Vpr comprising amino acids 17-36 and/or 59-84, as recited in Applicants'

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IV. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants' undersigned representative at (215) 564-8906 if there are any questions regarding Applicants' claimed invention. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Respectfully submitted,

Chad Ziegler
Registration No. **44,273**

Date: **July 9, 2002**

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-4 and 7 have been amended as follows:

1. (Amended twice) A conjugated composition comprising[:]

a fragment of HIV-1 Vpr comprising amino acid sequence 17-36 and/or 59-84 [or a non-HIV-1 Vpr protein comprising amino acids amino acids 17-36 and/or 59-84 of HIV-1 Vpr protein] conjugated to a therapeutic compound.

2. (Amended) The conjugated composition of claim 1 wherein said fragment of HIV-1 Vpr [or said non-HIV-1 Vpr protein] further comprises a polycationic amino acid sequence.

3. (Amended) The conjugated composition of claim 1 wherein said therapeutic compound is a DNA vaccine plasmid conjugated to said fragment of HIV-1 Vpr [or said non-HIV-1 Vpr protein] by ionic bonds.

4. (Amended) The conjugated composition of claim 1 wherein said fragment of HIV-1 Vpr [or said non-HIV-1 Vpr protein] further comprises a polycationic amino acid sequence and said therapeutic compound is a nucleic acid molecule which is conjugated to said polycationic amino acid sequence by ionic bonds.

7. (Amended) A method of delivering a compound to the nucleus of a cell comprising the step of:

contacting said cell with a conjugated compound that is either said compound conjugated to a fragment of HIV-1 Vpr protein comprising amino acids 17-36 and/or 59-84 [or said compound conjugated to a non-HIV-1 Vpr protein comprising amino acids 17-36 and/or 59-84 of HIV-1 Vpr protein]; wherein said conjugated compound is taken up by said cell and localized to the nucleus of said cell.